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| 09/724,857 | 11/28/2000 | Koen Weterings | 02307O-114700US | 7630 |

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| EXAMINER | |
|---|---|
| COLLINS, CYNTHIA E | |
| ART UNIT | PAPER NUMBER |
| 1638 | |

DATE MAILED: 12/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/724,857 | Applicant(s) WETERINGS ET AL. | |
|---|---|---|---|
| | Examiner Cynthia Collins | Art Unit 1638 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *05 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-80* is/are pending in the application.

4a) Of the above claim(s) *8,12,16,19,24-77,79 and 80* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-11,13-15,17,18,20-23 and 78* is/are rejected.

7)☒ Claim(s) *6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election with traverse of Group I, claims 1-7, 9-11, 13-15, 17-18, 20-23 and 78, drawn to an isolated polynucleotide of SEQ ID NO:1, in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the examination of Groups I-X would not create an undue burden on the Office. This is not found persuasive because the examination of Groups I-X would require a separate search for subject matter not common to each group of Invention. Accordingly, claims 8, 12, 16, 19, 24-77 and 79-80 are withdrawn from consideration as being directed to nonelected inventions.

The requirement is still deemed proper and is therefore made FINAL.

### *Claim Objections*

Claim 6 is objected to because claim 6 is directed to a nonelected invention (SEQ ID NO:6) in the alternative. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 9-11, 13-15, 17-18, 20-23 and 78 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a nucleotide sequence having at least 50% identity to nucleotides 3329 to 3475 of SEQ ID NO:1, a nucleotide sequence which hybridizes to nucleotides 3329 to 3475 of SEQ ID NO:1 under a condition establishing a $T_m$ minus 20° C, a nucleotide sequence having at least 50% identity to SEQ ID NO:1, nucleotide sequence which hybridizes to SEQ ID NO:1 under a condition establishing a $T_m$ minus 20° C, a polynucleotide comprising nucleotides 3324 to 3580 of SEQ ID NO:1, a polynucleotide comprising nucleotides 3324 to 3580 of SEQ ID NO:1, a nucleotide sequences comprising nucleotides 3329 to 3475 of SEQ ID NO:1, and a nucleotide sequence having at least 50% identity to SEQ ID NO:1 or a nucleotide sequence which hybridizes to SEQ ID NO:1 under a condition establishing a $T_m$ minus 20° C further comprising a G564 polynucleotide.

The specification discloses that a 4.2 kb G564 promoter region functions to drive transcription of a GUS reporter gene in transgenic tobacco embryos in the two suspensor cells of the preglobular stage embryo, the suspensor and hypophyseal region of the globular stage embryo, the axis of heart and torpedo stage embryos, and in the endosperm (page 62), but the specification does not explicitly state that the 4.2 kb G564 promoter region is the nucleotide sequence of SEQ ID NO:1. The specification also discloses that a suspensor-specific control element was determined to be present between positions –921 and –662 (page 62 and Figure 6), but the specification does not disclose in what way, if any, this suspensor-specific control element corresponds to SEQ ID NO:1. The specification additionally discloses the identification of three additional promoter fragments capable of driving suspensor specific gene expression from a minimal 35S promoter: a fragment from positions –1524 to –99, a fragment from positions –2064 to –99, and a fragment from positions –913 to –713 (page 63 and Figure 7), but

the specification does not disclose in what way, if any, these three additional promoter fragments correspond to SEQ ID NO:1.

Furthermore, the specification does not describe the structure of nucleotide sequences that function to promote transcription in suspensor cells and or the basal region of a plant embryo wherein the sequences have a nucleotide sequence at least 50% identity to nucleotides 3329 to 3475 of SEQ ID NO:1, a nucleotide sequence which hybridizes to nucleotides 3329 to 3475 of SEQ ID NO:1 under a condition establishing a $T_m$ minus 20° C, a nucleotide sequence having at least 50% identity to SEQ ID NO:1, nucleotide sequence which hybridizes to SEQ ID NO:1 under a condition establishing a $T_m$ minus 20° C, a polynucleotide comprising nucleotides 3324 to 3580 of SEQ ID NO:1, a polynucleotide comprising nucleotides 3324 to 3580 of SEQ ID NO:1, a nucleotide sequences comprising nucleotides 3329 to 3475 of SEQ ID NO:1, or a nucleotide sequence having at least 50% identity to SEQ ID NO:1 or a nucleotide sequence which hybridizes to SEQ ID NO:1 under a condition establishing a $T_m$ minus 20° C further comprising a G564 polynucleotide.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lily and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the

species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed products, any method of using them would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No.4/ Friday January 5, 2001/Notices: pp. 1099-1111).

Claims 1-7, 9-11, 13-15, 17-18, 20-23 and 78 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the exemplified isolated polynucleotides disclosed as functioning to promote transcription in suspensor cells and or the basal region of a plant embryo, does not reasonably provide enablement for other polynucleotides that are not disclosed as functioning to promote transcription in suspensor cells and or the basal region of a plant embryo. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to isolated polynucleotides, expression cassettes, vectors, host cells, plants and a method of introducing a polynucleotide into a host cell, said products and method being directed to a nucleotide sequence having at least 50% identity to nucleotides 3329 to 3475 of SEQ ID NO:1, a nucleotide sequence which hybridizes to nucleotides 3329 to 3475 of SEQ ID NO:1 under a condition establishing a $T_m$ minus 20° C, a nucleotide sequence having at

least 50% identity to SEQ ID NO:1, nucleotide sequence which hybridizes to SEQ ID NO:1 under a condition establishing a $T_m$ minus 20° C, a polynucleotide comprising nucleotides 3324 to 3580 of SEQ ID NO:1, a polynucleotide comprising nucleotides 3324 to 3580 of SEQ ID NO:1, a nucleotide sequences comprising nucleotides 3329 to 3475 of SEQ ID NO:1, and a nucleotide sequence having at least 50% identity to SEQ ID NO:1 or a nucleotide sequence which hybridizes to SEQ ID NO:1 under a condition establishing a $T_m$ minus 20° C further comprising a G564 polynucleotide.

The specification discloses that C564 is a Scarlet Runner Bean mRNA that accumulates specifically within the suspensor of globular-stage embryos, and that the exemplary promoter and promoter control elements of the C564 gene correspond to SEQ ID NO:1 and fragments thereof (pages 17-18). The specification also discloses that a 4.2 kb G564 promoter region was cloned upstream of a GUS reporter gene (page 55), and that the resultant construct was used to transform tobacco (page 62), but the specification does not explicitly state that the 4.2 kb G564 promoter region is the nucleotide sequence of SEQ ID NO:1. GUS expression was observed in transgenic tobacco embryos in the two suspensor cells of the preglobular stage, the suspensor and hypophyseal region of the globular stage, the axis of heart and torpedo stages, and in the endosperm (page 62). The pattern of GUS expression observed in transgenic tobacco embryos followed the same developmental pattern as observed for expression of the native gene in Scarlet Runner Bean embryos (page 62). The specification additionally discloses that a series of 5' deletions was made to identify the regions required for suspensor-specific expression, and that a suspensor-specific control element was determined to be present between positions –921 and –662 (page 62 and Figure 6), but the specification does not disclose in what way, if any, this suspensor-specific control element corresponds to SEQ ID NO:1. Three additional promoter

fragments capable of driving suspensor specific gene expression were identified. These three fragments, from positions –1524 to –99, from positions –2064 to –99, and from positions –913 to –713, were isolated and linked to a minimal 35S promoter operably linked to a GUS reporter gene (page 63 and Figure 7), but the specification does not disclose in what way, if any, these three additional promoter fragments correspond to SEQ ID NO:1.

Furthermore, the specification does not disclose nucleotide sequences that function to promote transcription in suspensor cells and or the basal region of a plant embryo wherein the sequences have a nucleotide sequence at least 50% identity to nucleotides 3329 to 3475 of SEQ ID NO:1, a nucleotide sequence which hybridizes to nucleotides 3329 to 3475 of SEQ ID NO:1 under a condition establishing a $T_m$ minus 20° C, a nucleotide sequence having at least 50% identity to SEQ ID NO:1, nucleotide sequence which hybridizes to SEQ ID NO:1 under a condition establishing a $T_m$ minus 20° C, a polynucleotide comprising nucleotides 3324 to 3580 of SEQ ID NO:1, a polynucleotide comprising nucleotides 3324 to 3580 of SEQ ID NO:1, a nucleotide sequences comprising nucleotides 3329 to 3475 of SEQ ID NO:1, or a nucleotide sequence having at least 50% identity to SEQ ID NO:1 or a nucleotide sequence which hybridizes to SEQ ID NO:1 under a condition establishing a $T_m$ minus 20° C further comprising a G564 polynucleotide.

Guidance for making and using the claimed invention is necessary for enablement because the ability of any particular nucleotide sequence to function as a promoter is highly unpredictable. Sequences homologous to or sequences that are contiguous subfragments of a nucleotide sequence also cannot predictably be assumed to have general or specific promoter activity. This unpredictability originates in the mechanics of promoter function, which requires the presence of particular nucleotides in the sequence to mediate a specific promoter function. As

a consequence, it is unpredictable whether a sequence having at least 50% sequence identity to a known tissue-specific promoter would retain specific promoter function, because it is unpredictable whether a sequence having at least 50% sequence identity to a known tissue-specific promoter would retain all the particular nucleotides necessary to mediate specific promoter function. It is also unpredictable whether a sequence which hybridizes to a known tissue-specific promoter would retain specific promoter function, because it is unpredictable whether a sequence which hybridizes to a known tissue-specific promoter would retain all the particular nucleotides necessary to mediate specific promoter function.

For example, Kim et al. teach that various point mutations in the *nos* promoter can alter the presence or level of promoter activity in tobacco. (Plant Molecular Biology, 1994, Vol. 24, pages 105-117). Mutation of one or more nucleotides in either of two hexamer motifs or in the octamer spacer region between them significantly altered the level of *nos* promoter activity (Table 2, page 109). For example, a single point mutation in the sixth nucleotide of the hexamer motif resulted in a four to ten fold decrease in promoter activity, whereas a double point mutation in the fourth and fifth nucleotide of the hexamer motif resulted in a two-fold increase in promoter activity. Two independent triple point mutations in the third, fourth and fifth, and sixth, seventh and eighth nucleotides of the octamer spacer region eliminated detectable promoter activity. These mutant promoter sequences differ from the native promoter sequence by only one to three nucleotides in a region that spans only 20 nucleotides, yet they vary greatly in the ability to function as a promoter. This is because promoter function occurs through direct interaction between particular individual promoter nucleotides and the regulatory proteins that bind them.

Additionally, it is unpredictable whether a particular subsequence of a known tissue-specific promoter would retain a tissue-specific function, because it is unpredictable whether a

subsequence of a known tissue-specific promoter would retain all the particular nucleotides necessary to mediate specific promoter function. For example, McDonald et al. teach that a 196 bp region of the *Arabidopsis* rbcS-1A promoter is sufficient to confer light-regulated expression on heterologous reporter genes in transgenic tobacco (1990, EMBO Journal, Vol. 9, pages 1717-1726). McDonald et al. identified at least two separate and distinct subsequences critical for light-regulated expression, the G box and the I box, in this 196 bp region (page 1720 Figure 3). Mutation of either the G box or the I box significantly reduced light induced reporter gene expression (page 1719 Figure 2B constructs P1-T, P3-6-T, page 1720 Figure 4 constructs P1-T, P3-6-T, page 1722 Figure 6 constructs P1, P3, P6, P3-6, page 1722 column 1 last paragraph through page 1723 column 1 first paragraph).

Because promoter function is directly mediated by particular individual nucleotides, the function of a promoter may be more readily affected by a single nucleotide change than the function of a coding sequence, which can accommodate a variety of nucleotide changes without an effect on polypeptide function due to the degeneracy of the genetic code. Because promoter function depends on the presence of particular individual nucleotides that interact with regulatory proteins to effect promoter function, the ability of any particular nucleotide sequence to function as a tissue-specific promoter is highly unpredictable. Because the ability of the claimed nucleic acid sequences to function as promoters in plant suspensor cells and/or the basal region of a plant embryo is not described by analogy or by working example, the full scope of the claimed invention is not enabled by the specification in the absence of further guidance or example.

Given the claim breadth, unpredictability, and lack of guidance as discussed above, it would require undue experimentation for one skilled in the art to determine which of the claimed

nucleic acid sequences to use in order to promote the transcription of an operably linked sequence in a plant suspensor cell and/or basal region of a plant embryo.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 6-7, 9-11, 13-15, 17-18, 20-23 and 78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2 and 6, and claims 3, 7, 9-11, 13-15, 17-18, 20-23 and 78 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "under a condition establishing a $T_m$ minus 20° C". It is unclear what condition would establish a $T_m$ minus 20° C. It is also unclear from what specific $T_m$ the 20° C would be subtracted.

Claims 1 and 6, and claims 2-3, 7, 9-11, 13-15, 17-18, 20-23 and 78 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "modulates". It is unclear how a polynucleotide would "modulate" transcription, as "modulate" implies a variety of different types of changes, such as increases and decreases, whereas the polynucleotides of the instant invention appear to promote or increase transcription.

Claim 9, and claim 10 dependent thereon, is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "G564". It is unclear what quality "G564" imparts on a polynucleotide that is operably linked to a promoter.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "G541". It is unclear what quality "G541" imparts on a polynucleotide that is operably linked to a promoter.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2, 4, 6, 17 and 78 are rejected under 35 U.S.C. 102(a) as being anticipated by SEQ ID NO:1 of Williamson et al. (US Patent No. 6,114,605, September 5, 2000).

The claims are drawn to isolated polynucleotides having at least 50% identity to nucleotides 3329 to 3475 of SEQ ID NO:1 or hybridizing to nucleotides 3329 to 3475 of SEQ ID

NO:1 under a condition establishing a $T_m$ minus 20° C or having at least 50% identity to SEQ ID NO:1, a host cell, and a method of introducing a polynucleotide into a host cell.

Williamson et al. teach an isolated polynucleotide of SEQ ID NO:1 having at least 50% identity to nucleotides 3329 to 3475 of SEQ ID NO:1 or hybridizing to nucleotides 3329 to 3475 of SEQ ID NO:1 under a condition establishing a $T_m$ minus 20° C or having at least 50% identity to SEQ ID NO:1. While Williamson et al. do not explicitly teach transcription modulation in a plant suspensor cell and/or basal region of a plant embryo, the preamble of claim 1 does not necessarily limit the claimed polynucleotides. Furthermore, a transcription modulation function in a plant suspensor cell and/or basal region of a plant embryo would be an inherent feature of any of the claimed polynucleotides. Additionally, the polynucleotide taught by Williamson et al. would necessarily have been introduced into a host cell during cloning.

Claims 1, 2, 4, 6, 17 and 78 are rejected under 35 U.S.C. 102(e) as being anticipated by SEQ ID NO:1 of Staskawicz et al. (US Patent No. 6,262,343, issued July 17, 2001 with an effective filing date of July 23, 1998).

The claims are drawn to isolated polynucleotides having at least 50% identity to SEQ ID NO:1, and a host cell.

Staskawicz et al. teach an isolated polynucleotide of SEQ ID NO:1 having at least 50% identity to SEQ ID NO:1. While Staskawicz et al. do not explicitly teach transcription modulation in a plant suspensor cell and/or basal region of a plant embryo, the preamble of claim 1 does not necessarily limit the claimed polynucleotides. Furthermore, a transcription modulation function in a plant suspensor cell and/or basal region of a plant embryo would be an inherent

feature of any of the claimed polynucleotides. Additionally, a host cell would necessarily have been used to clone the polynucleotide taught by Staskawicz et al.

***Remarks***

No claim is allowed.

Claims 3, 5, 7, 9-11, 13-15, 18 and 20-23 are deemed free of the prior art, given the failure of the prior art to teach or suggest an isolated nucleic acid of SEQ ID NO:1 or a host cell transformed therewith.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
December 2, 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638